

REMARKS

The Official Action of January 9, 2004 has been carefully considered and reconsideration of the application as amended is respectfully requested.

Claims 1, 3 and 4 directed to a food composition have been canceled and claims 11-27 directed to a method for use of the food composition have been rewritten as new claims 28-73. The claims presently on file are respectfully believed to be free of the rejections under 35 USC 112, second paragraph appearing at page 2 of the Official Action and are otherwise believed to be sufficiently definite to satisfy the dictates of 35 USC 112, second paragraph.

The claims were rejected under 35 USC 103(a) as allegedly being unpatentable over AU-A-63136/94 and WO 97/16977 or in view of this combination of references further in view of Clark et al and AU-A-39340/89. Applicant respectfully traverses these rejections and submits that the references do not set forth even a *prima facie* case of obviousness for the invention as now claimed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See MPEP Section 706.02(j). As next discussed, the

prior art references do not provide even a reasonable expectation of success with the claimed method whereby they do not set forth a *prima facie* case of obviousness at least for this reason..

As discussed in the present specification at, for example, page 5, paragraphs 2 and 3, as of the filing date of the present application, the commonly held belief among those skilled in the art (based on a prior art study) was that orally ingested colostrum would not have any affect on exercise performance. In contrast, Applicant postulated that the effectiveness of an orally ingested colostrum fraction would depend on the manner of preparation of the fraction (see specification at page 4, last paragraph, and paragraph 5, first paragraph). Applicant found, surprisingly, that with correct processing an orally ingested colostrum composition could enhance exercise performance and physical work capacity.

The claims presently on file are all directed to methods for changing body composition and/or physical work capacity, and all recite an administering step which is ingestion. They also all recite a specific colostrum composition comprising casein that is prepared by a specific process, as next discussed.

In the claimed method, the composition has been prepared by a specific process and as a consequence, certain advantages are derived which allow the colostrum product to change body composition and/or physical work capacity. The specific composition contains casein and is treated by spray drying which preserves

the essential ingredients which can assist in achieving the results indicated. It is the specific combination that remains after this process that derives the advantages of the colostrum product. Applicants believe that the casein may assist in preserving the essential components particularly in the gut after ingestion. The prior art such as Clarke et al. teaches removal of casein. In fact, casein is considered to be problematic when processing colostrum. Furthermore, spray drying is not a process that is generally used in processing of colostrum. Therefore the combination of casein and spray-drying colostrum after ultrafiltration results in a unique colostrum product. However, the colostrum product is still expected to contain various growth factors and proteins that are generally found in colostrum and which may contribute to changing body composition and physical work capacity.

However, as discussed above, it would not have been expected that the colostrum product would work if it were ingested. Any proteins or growth factors etc that are present in the colostrum would have been expected to be degraded in the gut and thereby to have no effect on changing body composition and physical work capacity. Surprisingly, the colostrum composition of the claimed invention does have an effect, as evidenced by the Examples in the specification. This was indeed an unexpected result: the manner in which the colostrum is processed and the resultant composition (which includes casein) are beneficial for providing a measurable effect on changing body composition and physical work capacity.

Colostrum when used by young animals is used only in the first few days after

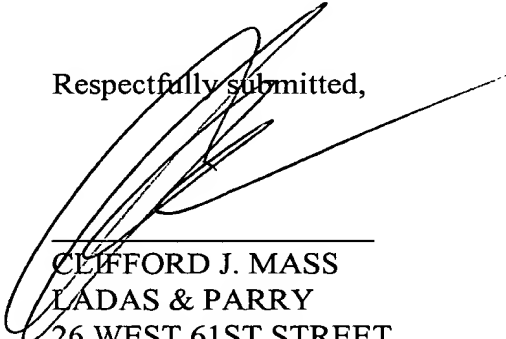
birth. After that period it has no effect. This is particularly evident in the pig when the gut has not closed and the essential components in colostrum can be used in a beneficial way. The applicants have shown the beneficial use of colostrum in Example 5 of the application. In piglets, the colostrum product produced by the process showed a significant improvement in the four week weight and overall growth rate of piglets compared to those fed in sow's milk supplement containing whey protein. Therefore the colostrum product (containing casein) may also be beneficial in an adult where the casein assists in protecting those components useful and beneficial to growth. In an adult, upon ingestion, degrading enzymes present in the gut would be activated and would be expected seriously to affect the beneficial effects of colostrum. Therefore, there would have been no expectation of success if the product were ingested. However, because the colostrum is processed in a particular way, applicants have found that there is a beneficial effect of the composition remaining that can be used to ingest and change body composition and/or physical capacity. Because of the ratio of components, the product is successful. This is an unexpected result.

The prior art raised by the Examiner does not teach a method to use the colostrum processed in this manner. Indeed, the Clarke et al reference does not even provide a colostrum which contains casein as required by the claims. Because the method recites a step of ingestion, it is not obvious to expect any beneficial effect arising from the claimed colostrum since degrading enzymes in an adult would be expected to severely affect any growth factors or components within colostrum which may have a beneficial affect in changing body composition and/or physical work

capacity. Accordingly, in the light of the prior art, there is no reasonable expectation of success and the references cannot be considered to set forth even a *prima facie* case of obviousness.

In view of the above, it is respectfully submitted that all rejections and objections of record have been overcome and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,



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